

STUDY NUMBER: 2500577 PART A

Dear pioneer,

A study to **treat hepatitis E infections** will soon start at our research centre in Edegem.

Are you interested in participating and giving science a boost?

Hereby we would like to give you an overview of the study: duration of **± 6 weeks**.

In this cohort, the study medication will be administered **orally** (by mouth).

INCLUSION CRITERIA

- **Last participation in other clinical study (final study visit*):** *not later than 12 weeks before the first administration of the study medication.*
 - **cohort 2a sentinel:** not later than **20MAY2026**
**Be careful: Final study visit of the previous study needs to be performed to be able to participate at screening.*
- Healthy men and women between age of 18 en 65 years (inclusive) at screening
- BMI: 18.0 – 29.0 kg/m² (inclusive) at screening
 - Weight at least 50.0 kg at screening
- Non-smoker or stopped smoking at least 6 months prior to day -2 (including e-cigarettes, nicotine patches, snuff, nicotine gum, etc.)
- Not using any medication, vitamins, or homeopathic substances (in consultation with the physician, it may be possible to continue taking certain medications during the study).
- Contraception:
 - **Fertile women:** *from screening until at least 30 days after administration of the medication*
 - Be willing to use an effective contraceptive method (the pill, IUD, contraceptive injection, patch, partner's vasectomy, etc.) in combination with an effective barrier method such as the male condom.
 - **OR** abstinence
 - **AND** be prepared not to donate eggs.
 - **Infertile women:**
 - postmenopausal (= no menstruation for at least 12 months)
 - **OR** removal of uterus
 - **OR** removal of both ovaries
 - **OR** removal of both fallopian tubes
 - **Men:** *from screening and until at least 90 days after the administration of the study medication*
 - If your partner is fertile: use a condom + use of an effective method of contraception by your partner
 - **OR** vasectomy
 - **OR** abstinence
 - **AND** be prepared not to donate sperm
- Willing to:
 - wear a holter monitor during the stay in the unit.
 - to eat a high-fat, high-calorie breakfast **completely**
- You will be asked to follow the restrictions regarding physical activity, consumption of grapefruit (juice), poppy seeds, caffeine-, xanthine and alcoholic products.
- You are not eligible if:
 - You participated in a previous cohort of study 2500577
 - You are lactose intolerant



INTEREST IN PARTICIPATING

Registration for this study only indicates your interest and does not obligate you to participate, nor us to include you as a participant.

Thank you in advance for your interest and we hope to welcome you soon for study 2500577 part A.

SGS CPU